

Remarks

Claims 41-48, 54-71, and 74-80 are pending in the subject application. Applicant gratefully acknowledges the Examiner's withdrawal of the finality of the rejections in the Office Action dated April 14, 2004. By this Amendment, Applicant has canceled claims 42-45, 55-60, 64-65, 68, 71, 74-75, and 80, amended claims 41, 54, 61-63, 66, 69, 76, 78, and 79, and added new claims 86-95. Support for the amendments and the new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 41, 46-48, 54, 61-63, 66, 67, 69, 70, 76-79, and 86-95 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant gratefully acknowledges the Examiner's indication that claim 70 is allowed.

Claims 41, 54, and 61 are rejected for "obviousness type" double patenting over claims 1-3 and 8 of U.S. Patent No. 5,916,751. Applicant respectfully submits that claims 41, 54, and 61 in the subject application are not obvious over claims 1-3 and 8 in the '751 patent. However, by this Amendment, Applicant has amended these claims to include the limitation of claim 42 (which is not included under this rejection). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 71 and 79 are rejected for "obviousness type" double patenting over claims 1 and 2 of U.S. Patent No. 6,683,156. Applicant respectfully submits that claims 71 and 79 in the subject application are not obvious over claims 1 and 2 in the '156 patent. However, by this Amendment, Applicant has canceled claim 71 and has amended claim 79 to delete reference to an ebaF protein, thereby leaving reference only to a peptide consisting of the amino acid sequence shown in SEQ ID NO. 3. Thus, Applicant respectfully asserts that the rejection is moot by these amendments. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 80 is rejected for "obviousness type" double patenting over claims 1-7 of U.S. Patent No. 6,294,662. Applicant respectfully submits that claim 80 in the subject application is not obvious over claims 1-7 in the '662 patent. Claim 80 has been canceled, thereby rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 41-48, 54-65, 68, 71, 74, 75, and 78-80 are rejected under 35 USC §112, first paragraph, as lacking adequate written description. The Examiner asserts that the subject specification does not provide adequate written support for species of the ebaf protein other than a human ebaf protein and polynucleotides encoding the human ebaf protein. Applicant respectfully asserts that the subject specification does provide adequate written description for various species of ebaf protein and polynucleotides encoding the same. However, by this Amendment, Applicant has amended independent claims 41, 54, 61, 62, and 63 to recite that the nucleic acid encodes a human ebaf protein. In determining whether an application satisfies the written description requirement of §112, the state of scientific knowledge must be taken into account. *Capon et al. v. Eshhar et al. v. Dudas*, 418 F.3d 1349 (Fed. Cir. 2005). Because the genetic code is known, once the amino acid sequence of a protein is known, then all possible nucleotide sequences encoding that protein are also known. Thus, identification of a polynucleotide by naming the protein or polypeptide it encodes can be sufficient written description of the polynucleotide where the sequence of the encoded protein is known in the art. Applicant notes, for example, that the Feinberg *et al.* patent (U.S. Patent No. 5,395,825), which is cited by the Examiner in the instant Office Action in a rejection under 35 USC §102, does not recite specific for TGF- $\beta$  sequences in the claimed method. The amino acid sequence of ebaf protein, and the sequence of the gene encoding it, were known in the art at the time of filing the subject application. Thus, a person of ordinary skill in the art would be aware of the sequence and, therefore, would understand that the Applicants were in possession of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 41, 45, 46, 54-56, 59, 61-64, 66, 68, 71, and 79 are rejected under 35 USC §102(b) as anticipated by Feinberg *et al.* (U.S. Patent No. 5,395,825). The Examiner asserts that the Feinberg *et al.* patent discloses a method for determining the presence or absence of an endometrial irregularity associated with infertility by screening for the presence of an ebaf protein. Applicant respectfully traverses this ground of rejection.

Applicant respectfully asserts that the Feinberg *et al.* patent does not teach or suggest Applicant's claimed invention. The Feinberg *et al.* patent is directed to methods pertaining to TGF- $\beta$ . However, by this Amendment, Applicant has amended independent claims 41, 54, 61, 62, and 63

to recite that the *ebaf* nucleic acid is RNA which is detected by way of Northern blot analysis (the limitation of claims 42 and 58) and PCR analysis (the limitation of claim 57). The Feinberg *et al.* patent does not teach or suggest detection of *ebaf* nucleic acid by use of Northern blot or PCR analysis. The Examiner acknowledges this by the fact that claims 42, 57, and 58 are not included under this rejection. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Claims 64, 66, 68, 69, and 71 are rejected under 35 USC §102(a) as anticipated by Meno *et al.* (1996). Claims 65 and 67 are rejected under 35 USC §103(a) as obvious over Meno *et al.* In addition, claims 74-78 are rejected under 35 USC §103(a) as obvious over Meno *et al.* further in view of Foster *et al.* (U.S. Patent No. 4,444,879). The Examiner asserts that Meno *et al.* teach a composition comprising a protein encoded by an *ebaf* nucleic acid, in addition to an isolated antibody that binds to a protein encoded by an *ebaf* nucleic acid. In regard to the Foster *et al.* patent, the Examiner asserts that Foster *et al.* teach the formulation of immunoassay kit reagents and asserts that it would have been obvious at the time of present invention to incorporate the antibodies disclosed in the Meno *et al.* reference into the immunoassay kits as taught by the Foster *et al.* patent. Applicant respectfully traverses these grounds of rejection.

Applicant respectfully asserts that the cited references do not teach or suggest Applicant's claimed invention. Claims 64, 65, 68, 71, 74, and 75 have been canceled, rendering the rejection of those claims moot. In regard to the rejection of claims 66, 69, 76, and 78, Applicant notes that those claims have been amended to recite that the peptide "consists of" the amino acid sequence of SEQ ID NO. 3. Applicant respectfully asserts that the Meno *et al.* reference does not teach or suggest an antibody or antisera that specifically binds to a peptide that consists of the amino acid sequence of SEQ ID NO. 3. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102(a) and 35 USC §103(a) is respectfully requested.

Claims 64, 66, 68, 69, and 71 are rejected under 35 USC §102(b) as anticipated by Wieczorek *et al.* (1995). The Examiner asserts that the Wieczorek *et al.* reference teaches a composition of antibodies that specifically bind to a protein encoded by an *ebaf* nucleic acid, as well as a composition comprising a protein encoded by an *ebaf* nucleic acid. Applicant respectfully traverses this ground of rejection.

Applicant notes that claims 64, 68, and 71 have been canceled by this Amendment, thereby rendering the rejection moot for those claims. In regard to claims 66 and 69, Applicant has amended those claims to specify that the antibody and antisera specifically binds to a peptide that "consists of" the amino acid sequence of SEQ ID NO. 3. Applicant respectfully asserts that the Wieczorek *et al.* reference does not teach or suggest antisera that specifically binds to a peptide that consists of the amino acid sequence of SEQ ID NO. 3. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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